

**DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN  
USED ACCORDING TO DIRECTIONS**

**4201. Misbranding of La Parfaite syringe. U. S. v. 161 Devices, etc. (F. D. C. No. 33280. Sample No. 1159-L.)**

**LIBEL FILED:** On or about June 12, 1952, Southern District of Florida.

**ALLEGED SHIPMENT:** On or about November 16, 1950, from Paris, France.

**PRODUCT:** 161 *La Parfaite syringes* in individual boxes at Highland City, Fla., together with a number of circulars entitled "Feminine Hygiene is made 100% Effective."

The device consisted of a porcelain fitting equipped with a rubber inlet tube and a rubber outlet tube. The rubber inlet tube had a number of openings near the tip and one opening at the very tip end. In operation, a supply of fluid under hydrostatic pressure would be forced into the vagina through the rubber inlet tube.

**RESULTS OF INVESTIGATION:** Upon receipt of the devices from France, the consignee, Mrs. Grace Kern, doing business as the Florida Hygienic Co., at Highland City, Fla., repackaged the devices into individual boxes, together with 1 copy of the above-mentioned circular which had been printed for the consignee.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the above-mentioned circular were false and misleading. The statements represented and suggested that use of the device was effective for insuring a sound, healthy body for women, enabling the penetration of a cleansing solution to all parts of the vaginal tract, preventing cancer which might be caused by bruising the uterus through use of other types of douching devices, and providing a safe method of douching. The device was not effective for the intended purposes, and it was not capable of fulfilling the promises of benefit made for it.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling since the jet of fluid emerging from the hole in the tip of the device would enter the uterus and cause injury.

The device was misbranded in the above respects while held for sale after shipment in interstate commerce.

**DISPOSITION:** November 16, 1953. Grace Kern, claimant, having filed an answer to the libel and later having withdrawn such answer, judgment of condemnation was entered and the court ordered that the devices and the labeling be destroyed.

**VIOLATIVE SALES OF PRESCRIPTION DRUGS**

**4202. Misbranding of pulvules containing a mixture of Seconal Sodium and Amytal Sodium. U. S. v. Arnold's Pharmacy, Inc., Richard Leipert, and Max Rosenthal. Motion denied to dismiss information and to suppress evidence. Plea of guilty. Fine of \$3 against corporation and \$300 against each individual. (F. D. C. No. 35098. Sample Nos. 37495-L, 37497-L, 37500-L.)**

**INFORMATION FILED:** May 28, 1953, District of New Jersey, against Arnold's Pharmacy, Inc., Newark, N. J., Richard Leipert, treasurer of the corporation, and Max Rosenthal, pharmacist.